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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,972	02/28/2002	Karoline Bechtold-Peters	I/1197	1212

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/085,972	Applicant(s) BECHTOLD-PETERS ET AL.	
	Examiner Gollamudi S Kishore, Ph.D	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment dated 9-24-04 is acknowledged.

Claims included in the prosecution are 1-6.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Weers et al (6,309,623).

Weers et al disclose particles of water-soluble drugs such as albuterol sulfate, cromolyn sodium and gentamicin sulfate coated with poloxamer or sorbitan esters such as sorbitan monooleate. The particles further contain solid sodium chloride and sodium phosphate. The aerodynamic diameter of the particles 1.23 microns (abstract, col. 17, lines 3-15; Examples III and IV on col. 32 and Example VIII on col. 35).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the particles in Weers are perforated microstructures and instant invention does not have any perforated microstructures. These arguments

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are not found to be persuasive since instant claims are drawn to either micronized or spray dried active ingredient and the claim language does not exclude perforated structures of Weers.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maitra (5,874,111) by itself or in combination with Pitt (5,354,934) cited in the previous

action or WO 91/16038.

As pointed out in earlier office action, Maitra discloses water-soluble drugs coated with poloxamer (abstract, Fig.1, claim 7). On col. 1, line 42 et seq., Maitra discusses the relationship between the size of the particles and the targeting at specific body sites. According to Maitra, nanoparticles of 200 nm diameter and above, have biodistribution dependent on their interaction with RES and the smaller particles are mostly taken up by cells other than Kupffer cells. Therefore, it would have been obvious to one of ordinary skill in the art to prepare particles of desired diameters to achieve the desired goal.

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Pitt while disclosing pulmonary delivery of erythropoietin (water soluble drug) teaches that the particle size is an important consideration in achieving particle deposition in the distal lung regions and that the effective particle diameter range is from approximately 0.5 to 5 micrometers (abstract, col. 5, line 61 through col. 6, line 3 and col. 7, lines 62-63).

Similarly, WO 91 while disclosing pulmonary delivery of polypeptide microparticles teaches that particle sizes are key factors to control the deposition region of the particles in the respiratory tract and advocates the sizes of 0.5 to 10 microns (abstract, page 2, second paragraph and page 4, 'summary of the invention' section). One of ordinary skill in the art would be motivated further to prepare particles of instant sizes since both references of Pitt and WO teach the effectiveness of particles of instant sizes in the deposition of drug at the distal lung regions.

5. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/16038 in combination with Baichwal (5,738,865).

As pointed out above, WO teaches pulmonary delivery of solid micronized particles of biologically active polypeptides with the sizes of 0.5 to 10 micrometers (pages 2-4). What is lacking in WO is the coating of the particles with sorbitan fatty acid esters or poloxamer.

Baichwal while disclosing powder insufflations formulations containing proteinaceous drugs and polysaccharides teaches that inclusion of a surfactant such as sorbitan esters and poloxamer modifies the release-controlling properties of the drug particles. The particle diameter ranges from 100 nanometers to 10 microns (abstract,

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col. 6, line 66 through col. 7, line 35; col. 7, line 43 through col. 9, line 32; col. 10, lines 64-68 and claims). It would have been obvious to one of ordinary skill in the art to coat the drug particles with the surfactants if the desired goal is to control the release rates of the drug particles based on the teaching of Baichwal.

6. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weers cited and for the reasons set forth above or Baichwal (5,738,865).

The teachings of Weers have been discussed above. Instant claims recite alcohol (sorbitan) esters as one of the surfactants. What are lacking in Weers are examples showing the use of sorbitan esters. However, it would have been obvious to one of ordinary skill in the art to use sorbitan esters, with a reasonable expectation of success, since Weers provides adequate guidance for the preparation of the particles.

Baichwal while disclosing powder insufflation formulations containing proteinaceous drugs and polysaccharides teaches that inclusion of a surfactant such as sorbitan esters and poloxamer modifies the release-controlling properties of the drug particles. The particle diameter ranges from 100 nanometers to 10 microns (abstract, col. 6, line 66 through col. 7, line 35; col. 7, line 43 through col. 9, line 32; col. 10, lines 64-68 and claims). It would have been obvious to one of ordinary skill in the art to coat the drug particles with the surfactants if the desired goal is to control the release rates of the drug particles based on the teaching of Baichwal.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments with regard to Weers have already been addressed

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by the examiner. Applicant argues that Baichwal does not provide any suggestion or motivation to modify the teachings of Weers. These arguments are not persuasive since Baichwal states that these agents modify the release rates of the drug particles and hence provide a motivation to modify the teachings of Weers.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK